SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Renacet 475 mg, film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Calcium acetate

Each film-coated tablet contains:
475 mg calcium acetate (anhydrous) equivalent to 120.25 mg calcium.

Excipient with known effect: Sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

white, round, convex film-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hyperphosphatemia associated with chronic renal insufficiency in patients undergoing dialysis.

4.2 Posology and method of administration

Dosage should be effected individually. Unless a different dose has been prescribed, adults should take no more than 14 Renacet 475 mg film-coated tablets daily.

To achieve optimal efficacy, Renacet 475 mg should be taken during or immediately after meals.

The recommended dose is:

with breakfast:	1 to 2 film-coated tablets Renacet 475 mg
with a snack:	1 to 2 film-coated tablets Renacet 475 mg

with a main meal: 2 to 6 film-coated tablets Renacet 475 mg
with supper: 2 to 4 film-coated tablets Renacet 475 mg

Renacet 475 mg should be taken with some liquid during or immediately after meals and must not be chewed.

Experience with children is not available.

4.3 Contraindications

Renacet 475 mg must not be used in patients with:
Hypersensitivity to the active substance or to any of the excipients listed in 6.1.

Hypophosphatemia, severe hypophosphatemia, hypercalcemia, hypercalciuria associated with calcium-containing kidney stones, decalcifying tumors and skeletal metastases, severe renal failure without dialysis treatment, constipation, known stenosis of the large intestine, osteoporosis due to immobilisation.

4.4 Special warnings and precautions for use

Treatment with Renacet 475 mg requires regular measurement of the serum calcium and serum phosphate levels. Under no circumstances should the calcium concentration multiplied by the phosphate concentration exceed 5.3 mmol/l since the frequency of extraosseous calcification increases if this value is exceeded.

To avoid an increase in serum calcium level beyond the normal range the intake of Renacet 475 mg should be monitored regularly when patients are already on preparations which contain calcium.

Patients with the rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Excipients
Renacet 475 mg contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially “sodium-free”.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant intake of Renacet 475 mg with other medicinal products may impair their absorption.

For numerous anionic medicinal agents, e.g. tetracyclines and doxycycline, quinolones (gyrase inhibitors), biphosphonates, fluorides and anticholinergics changes in absorption may occur. Interaction may also occur with vitamin D preparations. Therefore it is recommended that there should be an interval of 1-2 hours between the intake of Renacet 475 mg and other medicinal products.

An increased effect may occur with cardiac glycosides, a reduced effect may occur with calcium antagonists.

Concomitant administration of thiazides results in an increased risk of hypercalcemia. If the calcium level is increased, use of adrenaline may lead to severe cardiac arrhythmia.

Intake of larger quantities of calcium salts may cause a precipitation of fatty or bile acids as calcium soaps. This may impair the absorption of ursodeoxycholic acid and chenodeoxycholic acid as well as fats and fat-soluble vitamins.

4.6 Fertility, pregnancy and lactation

Pregnancy
Harmful effects on humans due to calcium taken during pregnancy have not been reported. However, the likelihood of hypercalcaemia is increased in pregnant women in whom calcium and vitamin D are co-administered.

Lactation
Harmful effects on humans due to calcium taken during lactation have not been reported.

Fertility
There are no data on the effects of calcium acetate on fertility available.

4.7 Effects on ability to drive and use machines

Renacet 475 mg has no effect on the ability to drive or use machines.

4.8 Undesirable effects

The following definitions apply to the incidence of undesirable effects:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

General disorders:

Uncommon:	Soft tissue calcification (e.g. in the fatty tissue under the skin) usually occurring only after many years of intake and frequently associated with increased blood calcium levels.

Cardiac/vascular disorders:

Uncommon:	Hypercalcemia, especially following overdosage.

Gastrointestinal disorders:

Rare: especially	Gastrointestinal disorders such as nausea and constipation, in case of too high dosages. If gastrointestinal side effects occur, treatment should be changed to calcium carbonate as appropriate.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Overdose would not be expected to cause gross hypercalcaemia except in patients taking excessive doses of vitamin D.

Measures in case of overdose: Discontinuation of the medicinal product and symptomatic treatment including lowering calcium levels e.g. administration of oral phosphates and non-saline laxatives such as lactulose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:	Drug for treatment of hyperphosphatemia
ATC-Code:	A12AA12

Calcium is an endogenous ion of the body essential for the maintenance of a number of physiologic processes. It participates as an integral factor in the maintenance of the functional integrity of the nervous system, in the contractile mechanisms of muscle tissue, in the clotting of blood, and in the formation of the major structural material of the skeleton.

A dynamic equilibrium occurs between blood calcium and skeletal calcium, homeostasis being mainly regulated by the parathyroid hormone, by calcitonin and by vitamin D.Variations in the concentration of ionised calcium are responsible for the symptoms of hyper/hypocalcaemia. Soluble calcium salts are commonly used in the treatment of calcium deficiency.

5.2 Pharmacokinetic properties

The pharmacokinetics of calcium and its salts are well known. Bioavailability of calcium acetate depends on the dissolution rate which is normally completed after 15 minutes. After 15 minutes the calcium acetate is released. The serum concentration of phosphate may decrease after interaction with calcium resulting in the formation of the less soluble calcium phosphate salts.

5.3 Preclinical safety data

Preclinical studies with calcium acetate are very limited and reveal no special additional risks to those already mentioned in other sections of the SPC. Preclinical effects were observed only at doses considered in excess of the maximum human dose.

6.1 List of excipients

Tablet core
Maize starch
Sucrose
Gelatin
Sodium starch glycolate (Type A)
Croscarmellose sodium
Magnesium stearate, vegetable

Film coat
Hypromellose
Refined castor oil
Saccharin sodium
Talc
Orange flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Pack sizes:

100 film-coated tablets

200 film-coated tablets

PVDC-coated PVC / aluminium foil blisters

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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